

## REMARKS

Beneficially, Applicant's invention provides consumers who have a specified (minor) discomfort with relief for the discomfort and indications of one or more nutritional supplements for supplementing nutrition. This enables them to self-regulate their consumption of nutritional supplements while relieving their discomfort. Applicant's invention saves consumers the additional cost, time and storage space needed for purchase and use of the separately enclosed discomfort relievers and nutritional supplements for supplementing nutrition of the prior art.

The amendment to the specification is for clarity.

Claims 26, 29-30, 33-35, 37-38, 40-44 and 46 have been rejected under 35 USC 112 as failing to comply with the enablement requirement. The Examiner states that the claims contain subject matter, which is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. He states that the instant specification does not provide sufficient information to practice the invention without undue experimentation. Additionally, the Examiner states that the instant claims recite the preferred nutritional supplement as vitamin C (see claim 27), however, vitamin C in Tsunoda works synergistically with ibuprofen in menstruation pain relief. He states that in Tsunoda vitamin C contributes to discomfort relieving of ibuprofen, so the invention is not enabled. The Examiner further states that the instant claims encompass "nutritional supplement not being adapted to aid in or contribute to discomfort relieving of the discomfort reliever, and said nutritional supplement not being adapted to aid in or contribute to reducing side effects of said discomfort reliever," which has been omitted from the claims as amended. Accordingly, Claims 26, 29-30, 33-35, 37-38, 40-44 and 46 are believed to comply with 35 USC 112.

Claims 26, 29-30, 33-35, 37-38, 40-44 and 46 have been rejected under 35 USC 112 first paragraph. The Examiner states that the specification does not enable discomfort reliever, except ibuprofen, naproxen, caffeine and acetaminophen recited in claim 32. The Examiner states that the specification does not provide enablement for other discomfort reliever suitable for the instant

invention. The Examiner states that the specification does not enable use of the invention commensurate in scope with the claims. The Examiner states that the specification fails to provide sufficient information to practice the invention without undue experimentation. The Examiner cites the eight factors of In re Wands 8 USPQ 2d 1400 (CAFC 1988) at 1404. The Examiner cites General Electric Company v Wabash Appliance 37 USPQ 466 (US 1938) at 469 and University of California v Eli Lilly 43 USPQ2d 1398 (CAFC1997) at 1406 regarding functional language. The Examiner states that Applicant fails to set forth criteria that define "a discomfort reliever not being adapted to aid in or contribute to nutrition supplementing of said nutritional supplement," which has been omitted from the claims as amended. Accordingly, claims 26, 29-30, 33-35, 37-38, 40-44 and 46 are believed to comply with the enablement requirement of 35 USC 112.

Claims 26, 29-30, 33-35, 37-38, 40-44 and 46 have been rejected under 35 USC 112 second paragraph as being indefinite and failing to particularly point out the invention. The Examiner states that "associated with" renders the claims indefinite. "Associated with" has been omitted from the claims as amended. The Examiner states that "indicating" is not clear. The claims have been amended to provide an enclosure having indications for "indicating". The Examiner states that "other" renders the claims indefinite. "Other" has been omitted from the claims as amended. The Examiner states that "recommended" and "herb" render the claims indefinite. "Recommended" and "herb" have been omitted from the claims as amended. The Examiner states that "indicator" renders the claims indefinite. "Indicator" has been omitted from the claims as amended. Accordingly, claims 26, 29-30, 33-35, 37-38, 40-44 and 46 as amended are believed to comply with the requirements of 35 USC 112.

#### LACK OF ANY TEACHING FOR THE COMBINATION OF REFERENCES

Claims 26-30, 32-35 and 37-45 have been rejected under 35 USC 103 as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al in view of Krause. Beneficially, Applicant's invention provides a unit dose of discomfort

reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition, a percent of a daily value for a nutritional supplement and/or instructions for consuming the unit dose for supplementing nutrition. A proper combination of references requires a teaching in the references to suggest the combination thereof, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983), and cannot be based on forbidden hindsight, In re Rouffet 47 USPQ2d 1453, 1458 (CAFC, 1998). SS Pharmaceutical, and Tsunoda, and Yeh et al disclose pharmaceutical medication (cold, menstruation and/or periodontal). The Examiner states that Krause discloses food product labeling. Pharmaceutical medication (cold, menstruation and/or periodontal) is not disclosed by Krause. Neither food, food product labeling, nutrition nor supplementing nutrition is disclosed by SS Pharmaceutical, Tsunoda, or Yeh et al. There is no teaching in SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest the combination thereof to provide the method claimed by Applicant. This lack of a showing of motivation for combining references cited in the rejection is clear error, In re Sernaker, and is based on forbidden hindsight, In re Rouffet. Accordingly, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause is clearly improper.

#### THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION OF APPELLANT'S INVENTION

A problem with the rejection is that nowhere in any reference is there any suggestion to provide a unit dose of discomfort reliever (with or without an antioxidant and/or synergistic part of the discomfort reliever) with indications indicating supplementing nutrition. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for a nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. To say that this would have

been obvious is to resort to impermissible hindsight, In re Marshall 198 USPQ 344 at 346-347 (CCPA, 1978).

Cold medication in SS Pharmaceutical, menstruation medication in Tsunoda, periodontal medication in Yeh et al and food labeling in Krause are isolated disclosures. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). The Examiner has picked and chosen among isolated disclosures in the prior art for medication, and isolated disclosures in the prior art for food labeling. It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause of the rejection is legal error.

#### INDICATIONS OF SUPPLEMENTING NUTRITION IN A UNIT DOSE OF DISCOMFORT RELIEVER

Applicant claims a method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition, which encloses the unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. Neither SS

Pharmaceutical, Tsunoda, Yeh et al nor Krause disclose a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition, as required by Applicant's claims. Accordingly, the claims are not unpatentable over SS Pharmaceutical in view of Tsunoda, Yeh et al and Krause.

#### SUPERIOR RESULTS

Benefits provided by the invention claimed in the above captioned patent application, which are not provided by the applied prior art include: a unit dose of discomfort reliever in an enclosure having indications indicating a percent daily value for nutritional supplement in a unit dose of discomfort reliever. A practical significance of Applicant's invention, compared to the applied prior art, is that the user has discomfort relief and an indication of a percent daily value for the nutritional supplement in each unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort. This is a superior result. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). The applied medication prior art discloses discomfort relief, but not supplementing nutrition. Applicant's claimed invention provides superior results by relieving discomfort and indicating a percent daily value for a nutritional supplement in each unit dose thereby providing the ability to self regulate nutritional benefits while alleviating a discomfort. Accordingly, the rejection of the claims as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is improper. Patentability is shown beyond the requirements of the statute.

#### THE APPLIED REFERENCES TEACH AWAY FROM THE INVENTION

The nutritional disclosure of Krause does not disclose discomfort reliever. The applied medication prior art discloses antioxidant and/or synergistic vitamins as part of pharmaceuticals, as see SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) and Yeh et al (column 2, lines 5 and 31-37). Disclosure of antioxidant and/or synergistic vitamins as part of a pharmaceutical essentially teaches away from the invention, which requires a unit dose of a

discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating supplementing nutrition with a nutritional supplement; a percent of a daily value for the nutritional supplement in the unit dose and/or the indications indicating instructions for consuming the unit dose for supplementing nutrition. Krause does not disclose discomfort reliever. The applied medication prior art does not disclose supplementing nutrition. Disclosure of antioxidant and/or synergistic vitamins as part of a pharmaceutical essentially teaches away from the invention. This is a per se demonstration of prima facie nonobviousness, In Re Dow Chemical Co. 5 USPQ 2d 1529 (CAFC), 1988. Accordingly, claims 26-30, 33-35 and 37-46 are not prima facie obviousness over the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

The applied medication prior art discloses antioxidant and/or synergistic vitamins as part of pharmaceutical medications (cold, menstruation and/or periodontal). The applied medication prior art does not disclose nutrition, or indicating supplementing nutrition, as claimed by Applicant. This disclosure of antioxidant and/or synergistic vitamins as part of pharmaceutical medications, (and without disclosure of supplementing nutrition), essentially teaches away from the method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition, as claimed by Applicant, and is a per se demonstration of prima facie nonobviousness, In Re Dow Chemical Co. Accordingly, the claims are not prima facie obviousness over the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

The applied medication prior art discloses antioxidant and/or synergistic vitamins as part of pharmaceuticals medications (cold, menstruation and/or periodontal). The applied medication prior art does not disclose supplementing nutrition, or indicating a nutritional supplement as being provided to supplement nutrition, as claimed by Applicant, as see SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) and Yeh et al (column 2, lines 5 and 31-37). Disclosure of antioxidant and/or synergistic vitamins as part of a pharmaceutical is not a disclosure of supplementing nutrition. Thus, it is not in

the nutritional supplement field or pertinent to the supplementing nutrition problem with which Applicant's invention is involved. Similarly, Krause discloses nutrition labeling without any disclosure in the discomfort reliever field or pertinent to the discomfort relieving problem with which Applicant's invention is involved. This direction to only one or the other of the fields without pertinence to the combined problem with which Applicant's invention is involved, essentially teaches away from the invention. This is a per se demonstration of prima facie nonobviousness, In Re Dow Chemical. Accordingly, the claims are not prima facie obviousness over the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

THE APPLIED REFERENCES DO NOT DISCLOSE THE FEATURES OF THE CLAIMED INVENTION OR ANY BENEFIT FROM THE USE THEREOF

The court has held that the absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). All of the claims explicitly require a method of providing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating a percent of a daily value for nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The applied prior art does not disclose a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) and Yeh et al (column 2, lines 5 and 31-37) disclose including antioxidant and/or synergistic vitamins as part of a pharmaceutical medication (cold, menstruation and/or periodontal). Krause does not disclose a discomfort reliever. The applied medication prior art does not disclose or teach including any amount of antioxidant and/or synergistic vitamins beyond that, which is part of a pharmaceutical medication (cold, menstruation and/or periodontal). Nor does the applied medication prior art disclose or teach any amount of any antioxidant and/or synergistic vitamin for nutrition. Additionally, the applied medication prior art does not disclose a discomfort reliever in an enclosure having indications indicating supplementing nutrition. The applied medication prior art does not

disclose indications indicating a daily value for supplementing nutrition for any amount of the antioxidant and/or the synergistic portion of the pharmaceutical. In the applied medication prior art, pharmaceutical antioxidant and/or synergistic vitamins are not disclosed as being provided to supplement nutrition. Nor are they disclosed as providing a daily value for a nutritional supplement. So, one of ordinary skill in the pharmaceutical art would not indicate an antioxidant and/or synergistic vitamin as being provided for supplementing nutrition. Thus, the applied prior art references do not disclose or teach a method of enclosing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition, as claimed by Appellant. These explicit requirements of the claims are not disclosed by SS Pharmaceutical, Tsunoda, Yeh et al or Krause. The absence from all of the applied references of these explicit requirements of the claims makes the rejection erroneous and improper, In re Evanega. Accordingly, all of the claims are not unpatentable under 35 USC 103 over SS Pharmaceutical in view of Tsunoda, Yeh et al and Krause.

Additionally, the applied prior art does not provide the benefits of the invention. Beneficially, the invention provides the user with an indication of a percent of a daily value for nutritional supplement in the unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort.

#### ALL THE LIMITATIONS OF A CLAIM MUST BE CONSIDERED MEANINGFUL

All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Applicant's claims require a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. These features are not disclosed by the applied prior art. Indicating supplementing nutrition for in a unit



dose of discomfort reliever is a new and additional feature, which is not disclosed in the applied art. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. The rejection does not meaningfully consider all of the limitations of the claims. Accordingly, the claims are not unpatentable over SS Pharmaceutical Tsunoda, Yeh et al and Krause.

Krause discloses labeling for food (see page 277, last paragraph). Food contains protein, fat, carbohydrate, and has an energy value, see Krause page 279, right column, first paragraph. The disclosure in Krause of food, protein, fat, or carbohydrate, and energy value is not a basis for relieving a discomfort, as is required by Applicant's claims. The applied medication prior art does not disclose food, protein, fat, carbohydrate, or energy values. The applied medication prior art discloses pharmaceuticals having antioxidant and/or synergistic vitamins, as part of the pharmaceuticals. Any optimization of these antioxidant and/or synergistic vitamins, as part of the pharmaceuticals disclosed by the applied medication prior art, would be for their antioxidant and/or synergistic functions in the pharmaceuticals. By contrast, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35 and 37-46 as unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

The applied medication prior art discloses pharmaceuticals, which include antioxidant and/or synergistic vitamins, as see Yeh et al, column 2, lines 5 and 31-37. These antioxidant and/or synergistic vitamin(s) are disclosed as part of the pharmaceutical. Disclosure of an antioxidant and/or a synergistic vitamin as part of a pharmaceutical is not a basis for indicating a nutritional supplement is being provided to supplement nutrition, as claimed by Applicant. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35 and 37-46 as

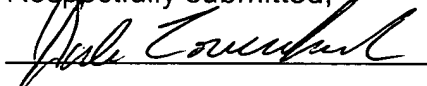
unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

#### TOPICAL TREATMENTS

Yeh et al discloses topical treatment of periodontal disease with a synergistic anti-inflammatory and antioxidant, as see column 1, lines 6-7 and column 2, lines 1-12. Yeh et al does not disclose supplementing nutrition or indicating a daily value for a nutritional supplement. Furthermore, topical treatments are not orally consumable as defined and used in the above captioned patent application. Orally consumable material are defined the above captioned patent application at page 4. Orally consumable material as defined in the above captioned patent application are not disclosed by Yeh et al. Accordingly, the claims are not unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

The claims are believed to be allowable. Such action is respectfully requested.

Respectfully submitted,



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